UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF ILLINOIS

IN RE: YASMIN AND YAZ (DROSPIRENONE) MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	)	**3:09-md-02100-DRH-PMF**
	)	**MDL No. 2100**

This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER NUMBER 48

Regarding Motions to Exclude Testimony of Plaintiffs' Expert Witness David Green, M.D., Ph.D. (MDL 2100 Doc. 2020)

I. INTRODUCTION

Defendants Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG ("Bayer") move to exclude the testimony of sixteen of the MDL plaintiffs' proffered experts. This Order addresses Bayer's motion to exclude the testimony of David Green, M.D., Ph.D. (Doc. 2020). Familiarity with the underlying proceeding is presumed. For the reasons that follow, Bayer's motion is **DENIED** on all grounds raised.

II. BACKGROUND

This multidistrict litigation (MDL) relates to the manufacture, marketing, and sale of the prescription pharmaceuticals known as YAZ and Yasmin.[1] YAZ and Yasmin, which are manufactured, marketed, and sold by Bayer, are members of a class of prescription medicines known as combined hormonal oral contraceptives ("COCs"), which contain both an estrogen and a progestin component (Doc. 2090 p. 6). The vast majority of COC's, including YAZ and Yasmin, contain the same type of estrogen–ethinyl estradiol (EE). *Id.*[2] In contrast to estrogen, the progestins in COCs are of many types. The progestin in YAZ and Yasmin is a newer type of progestin known as drospirenone ("DRSP"). *Id.*

DRSP-containing COCs are known as "fourth-generation" COCs (classified by the type of progestin used). *Id.* at pp. 6-5. COCs containing earlier developed progestins are categorized as "first-generation," "second-generation," and "third-generation." *Id.* at p. 6. First-generation COCs contain the progestin norethynodrel. *Id.* Second-generation COCs contain the progestin Levonorgestrel

[1] This MDL relates to other oral contraceptives that, like YAZ and Yasmin, contain drospirenone. However, YAZ and Yasmin are the subject drugs involved in the pending bellwether trials.

[2] YAZ and Yasmin differ in their dosing schedule and the amount of estrogen they contain. The Food and Drug Administration (FDA) approved YAZ and Yasmin as oral contraceptives in 2006. The FDA subsequently approved YAZ and Yasmin as a treatment for moderate acne vulgaris in women who choose to use an oral contraceptive and as a treatment for premenstrual dysphoric disorder (PMDD) in women who choose to use an oral contraceptive.

("LNG") and third-generation COCs contain several progestins, including desogestrel, gestodene, and norgestimate ("NGM"). *Id*.

It is generally accepted that there is an increased risk of venous thromboembolic (VTE) disease (disease relating to blood clotting in the veins) in COC users (Doc. 2102-14 p. 5; Doc. 2090-2 p. 2). It is also generally accepted that second-generation COCs (LNG-containing COCs) are considered to have a low risk for VTE disease (Doc. 2102-14 p. 6). Because the VTE risk associated with second-generation COCs is relatively low, LNG-containing COCs are often selected as a reference treatment in comparative studies evaluating whether there is an association between third-generation COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-4) and in comparative studies evaluating whether there is an association between DRSP-containing COCs and an increased risk of VTE disease (*See e.g.*, Doc. 2102-14 pp. 5-6). In the mid-1990s, various reports indicated that users of third-generation COCs were at higher risk of VTE disease than users of second-generation COCs (Doc. 2090-2 p. 2).[3]

At issue in this litigation is the safety of DRSP-containing COCs and whether the use of DRSP is associated with a higher risk of VTE disease. Specifically, Plaintiffs contend that Bayer misrepresented or omitted facts pertaining to the safety and efficacy of YAZ and Yasmin. With respect to the safety of YAZ and Yasmin, plaintiffs contend that the DRSP component of the drugs is associated with an increased risk of VTE disease and of potentially life-threating

[3] Plaintiffs note that the third-generation COCs include labels advising doctors that "[s]everal epidemiologic studies indicate that third generation oral contraceptives . . .are associated with a higher risk of venous thromboembolism than certain second generation oral contraceptives."

thrombosis complications, including deep vein thrombosis (DVT) (a blood clot formation in one of the body's deep veins) and pulmonary embolism ("PE") (a clot formation that travels to the lungs).[4]

A. Proffered Testimony of Dr. David Green

This Order addresses Bayer's motion to exclude the testimony of Plaintiffs' proffered expert, Dr. Green (Doc. 2020) to which Plaintiffs have filed a response (Doc. 286) and Bayer a reply (Doc. 2130). The record reveals that David Green, M.D., Ph.D., is a hematologist and medical researcher and an Attending Physician, and Clinical Assistant Professor of Medicine at New York University School of Medicine. He directs a coagulation laboratory at the School of Medicine.

Plaintiffs seek to have Dr. Green testify as an expert regarding the thrombotic risk of fourth-generation DRSP-containing COCs (the "fourth-generation such as Yaz and Yazmin). Dr. Green's testimony will be that the risk of the fourth-generation COCs is at least[5] the equivalent of oral contraceptives ("OC") containing third-generation progestins (See Green Report at 6—Doc. 2020, Ex. A).

[4] Plaintiffs also contend that Bayer misrepresented the benefits of YAZ and Yasmin with respect to treatment of premenstrual syndrome ("PMS"), acne and premenstrual dysphoric disorder ("PMDD") and that YAZ and Yasmin are defectively designed because safer alternative designs exist. These contentions are not addressed by Dr. Green's proffered opinions.

[5] Dr. Green's specific conclusion is that "the totality of the evidence from epidemiologic studies, as well as the scientific literature and clinical data, support the conclusion that the thrombotic risk of DRSP-containing COC is at least equivalent to a third generation progestin containing OC." (Doc. 2020, ex. A, p. 7)

In his report,[6] Dr. Green notes that DVT can be challenging to diagnose due to the "nonspecific nature of symptoms." (Green Report at 2). He further notes that the risk of VTE in non-COCs users is 0.8 per 10,000 women/year which rises to 3.0 per 10,000 women/year in OC users. He further notes that the VTE risk is greatest in the first year of use. (*Id.* at 2) Dr. Green includes a Danish national study and a more recent European Medicines Agency reappraisal which compared second-generation COC VTE rates to fourth-generation COC VTE rates. He notes that the conclusion of the comparison was that fourth-generation COCs had a risk rate similar to third-generation COCs. (*Id.* at 3-4.)

Dr. Green's report provides that contraceptive hormones induce complex changes in coagulation factors, inhibitors and in the components of the fibrinolytic (the natural process that prevents blood clots from growing) pathway. (*Id.* at 6.) Dr. Green, relying, in part, on prior studies, provides that the second-generation COCs had a higher anti-estrogenicity than either the third-generation or fourth-generation COCs. Sex hormone binding globulin (SHBG) levels rise with estrogen exposure, and higher SHBG levels correlate with increased hormone-induced VTE risk. (*Id.*) Although the mechanism which triggers hormone induced venous thrombosis is not known, there is an observed resistance to the anticoagulation effect of activated protein C (APC). There is also a recognized link between estrogen levels (which decrease protein S and tissue factor pathway inhibitor ("TFPI") both of which are necessary for anti-coagulation), and resistance

[6] Dr. Green's report is not numbered. However, the Court will (as the parties did at Dr. Green's testimony) refer to the report pages starting with the first page of text as "page 1." (See, Green Depo. at 21-22).

to APC, which, in turn, is associated with elevated VTE risk. (Green Report at 6). Dr. Green relies, in part, on the Rosing assay, 2010, in making this connection.

B. Bayer's Challenges to Dr. Green's Testimony

Bayer contends that the Dr. Green's opinion fails to meet the requirements for admissible expert testimony under Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharm. Inc.*, 509 U.S. 579 (1993) (*Daubert*). Specifically, Bayer seeks to preclude Dr. Green's testimony contending that the matters on which the plaintiffs seek his opinion are beyond Dr. Green's expertise, unreliable, irrelevant, prejudicial, and/or exceed the scope of permissible expert testimony.

The Court notes that Bayer does not contest Dr. Green's qualifications as either a clinician or researcher, nor the relevance of his testimony to the matters at issue in this case.

Bayer challenges Dr. Green's testimony generally on the grounds his opinions fail to meet the requirements for admissible expert testimony under Federal Rule of Evidence 702 and *Daubert*. Specifically, Bayer seeks to preclude all testimony by Dr. Green asserting the following: 1. that Dr. Green's opinion based on the Rosing Assay is inadmissible because the Rosing Assay (which correlates APC resistance to a VTE risk) is not an accepted test; 2. that Dr. Green is not an expert in SHBG markers as a risk for VTE, and therefore cannot opine as to this connection; 3. that Dr. Green improperly opines about the European regulatory proceeding; and, 4. That Dr. Green cannot rely on epidemiologic

research showing an increased VTE risk associated with DRSP-containing COCs because he is not an epidemiologist.

III. Legal Standard

FEDERAL RULE OF EVIDENCE 702, and *Daubert*, govern the admissibility of expert testimony. The *Daubert* standard applies to all expert testimony, whether based on scientific competence or other specialized or technical expertise. *Smith v. Ford Motor Co.*, 215 F.3d 713, 719 (7th Cir. 2000) (citing *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S.137, 141 (1999)). Rule 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. *Daubert* clarified that Rule 702 charges the district court with the task of ensuring that expert testimony is both relevant and reliable. *Daubert*, 509 U.S. at 589. This is commonly referred to as the "gatekeeper" role of the court. *See, e.g. Banister v. Burton*, 636 F.3d 828, 831 (7th Cir. 2011)(where the court stated that "it is the district court's role to act as gatekeeper before admitting expert scientific testimony in order to 'ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable.'")

Courts in the Seventh Circuit conduct a three-step analysis. *Ervin v. Johnson & Johnson, Inc.*, 492 F.3d 901, 904 (7th Cir. 2007).[7] First, the district court must determine whether the person whose testimony is offered is in fact an expert, as codified in Rule 702 through "knowledge, skill, experience, training or education." *Id.* (citing Fed. R. Evid. 702). Notably, "extensive academic and practical expertise" sufficiently qualify a potential witness as an expert, *Bryant v. City of Chicago*, 200 F.3d 1092, 1098 (7th Cir. 2000), and "Rule 702 specifically contemplates the admission of testimony by experts whose knowledge is based on experience," *Walker v. Soo Line R.R. Co.*, 208 F.3d 581, 591 (7th Cir. 2000). *Smith*, 215 F.3d at 718 (citing *Kumho*, 526 U.S. at 156 ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience.")).

Second, the district court must determine that the expert's reasoning or methodology is reliable. *Ervin*, 492 F.3d at 904; *see Mihailovich v. Laatsch*, 359 F.3d 892, 918 (7th Cir. 2004) (citing *Kumho*, 526 U.S. at 147). Specifically, the testimony must have a reliable basis in the knowledge and experience of the relevant discipline, *Kumho*, 526 U.S. at 149 (internal quotations removed), consisting of more than just a subjective belief or unsupported speculation.

[7] The Court notes the Seventh Circuit has also described the *Daubert* analysis as a two-step process. *See Chapman v. Maytag Corp.*, 297 F.3d 682, 686 (7th Cir. 2002). However, *Chapman* combines the first two steps described in *Ervin* as a single test of reliability, therefore, whether the analysis is described as a three-step or two-step process does not substantively change the Court's analysis.

Chapman v. Maytag Corp., 297 F.3d 682, 687 (7th Cir. 2002); *Daubert*, 509 U.S. at 590.

Further, as to reliability, *Daubert* provided the following non-exhaustive list of relevant factors: "(1) whether the scientific theory can be or has been tested; (2) whether the theory has been subjected to peer review and publication; (3) whether the theory has been generally accepted in the scientific community." *Ervin*, 492 F.3d 901, 904 (7th Cir. 2007) (citing *Daubert*, 509 U.S. at 593-94). However, there is no requirement that courts rely on each factor, as the gatekeeping inquiry is flexible and must be "tied to the facts" of the particular case. *Kumho*, 526 U.S. at 150 (quoting *Daubert*, 509 U.S. at 591); *see also Chapman*, 297 F.3d at 687. Thus, "the role of the court is to determine whether the expert is qualified in the relevant field and to examine the methodology the expert has used in reaching his [or her] conclusions." *Smith*, 215 F.3d at 718 (citing *Kumho,* 526 U.S. at 153).

The district court possesses "great latitude in determining not only *how* to measure the reliability of the proposed expert testimony but also whether the testimony is, in fact, reliable." *United States v. Pansier*, 576 F.3d 726, 737 (7th Cir. 2009) (citing *Jenkins v. Bartlett*, 487 F.3d 482, 489 (7th Cir. 2007)). Accordingly, the court's gatekeeping function requires focus on the expert's methodology; "[s]oundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact." *Smith*, 215 F.3d at 718 (citing *Daubert*, 509 U.S. at 595; *Walker,* 208 F.3d at 587). An expert must explain the

methodologies and principles that support his or her opinion, and cannot simply assert a "bottom line" or *ipse dixit* conclusion. *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010) (quoting *Minix v. Canarecci*, 597 F.3d 824, 835 (7th Cir. 2010)).

Finally, the district court must consider whether the proposed testimony will assist the trier of fact in its analysis of any issue relevant to the dispute. *See Smith*, 215 F.3d at 718; *Chapman*, 297 F.3d at 687; *Daubert*, 509 U.S. at 592. It is crucial that the expert "testify to something more than what is 'obvious to the layperson' in order to be of any particular assistance to the jury." *Dhillon v. Crown Controls Corp.,* 269 F.3d 865, 871 (7th Cir. 2001) (quoting *Ancho v. Pentek Corp.,* 157 F.3d 512, 519 (7th Cir. 1998)). However, the expert need not have an opinion as to the ultimate issue requiring resolution to satisfy this condition. *Smith,* 215 F.3d at 718 (citing *Walker*, 208 F.3d at 587).

Resolution of an expert's credibility or the correctness of his or her theories under the particular circumstances of a given case is a factual inquiry, left to the jury's determination after opposing counsel has cross-examined the expert at issue as to the conclusions and facts underlying his or her opinion. *Id.* (citing *Walker*, 208 F.3d at 589-90). Thus, "[i]t is not the trial court's role to decide whether an expert's opinion is correct. The trial court is limited to determining whether expert testimony is pertinent to an issue in the case and whether the methodology underlying that testimony is sound." *Id.* (citing *Kumho*, 526 U.S. at 159 (Scalia, J., concurring) (stating that the trial court's function under *Daubert*

is to exercise its discretion "to choose among reasonable means of excluding expertise that is fausse and science that is junky")).

IV. ANALYSIS

An understanding of the blood-clotting process (coagulation) is a necessary prerequisite for evaluating the proffered opinions. The following is a *simplified* overview of the elements and mechanisms at work in this process. The synopsis is based on the parties' pleadings and on a number of the experts' reports.

Blood clotting or coagulation is a vital step in the process that causes bleeding to stop. Coagulation begins after an injury to the blood vessel damages the vessel wall and exposes the blood to a protein known as tissue factor (TF). This exposure initiates a sequence of interactions involving various plasma proteins that ultimately lead to clot formation. The final step in the process occurs when a key enzyme in blood clot formation, thrombin, converts the fibrogen protein into fibrin, a "sticky" protein that is polymerized to form a blood clot. Once bleeding stops, anticoagulant factors must be activated to stop the clotting process. If the clotting process is not stopped it will continue and may result in a life-threatening blood clot such as DVT or a pulmonary embolism ("PE"). The protein C pathway and several anticoagulant proteins, including activated protein C (APC) and protein S, are an integral part of this process.

Functional defects in protein C pathway can be detected using various laboratory tests. Generally, these laboratory tests assess the anticoagulant response of plasma (the liquid in which the blood cells travel) to the addition of

APC. Since APC acts as an anticoagulant, a higher resistance to APC (or APC resistance) is thought to indicate a higher risk of venous thrombosis. APC resistance can be inherited or acquired. Oral contraceptive use is an acquired condition that has been associated with APC resistance.

A. Relevant Scientific Principles: Coagulation and APC-resistance Testing

Blood clotting or coagulation is a critical to hemostasis, the process that causes bleeding to stop. Coagulation begins after an injury to the blood vessel damages the vessel wall and exposes the blood to a protein known as tissue factor (TF). This exposure initiates a sequence of interactions involving various plasma proteins that ultimately lead to clot formation. The final step in the process occurs when a key enzyme in blood clot formation, thrombin, converts the fibrogen protein into fibrin, a "sticky" protein that is polymerized to form a blood clot.

Once bleeding stops, anticoagulants must be activated to stop the clotting process. Activated protein C (APC) is one of several anticoagulants involved in negating the clotting process. Because APC acts as an anticoagulant, plasma (the liquid in which the blood cells travel) that is resistant to APC may indicate an increased risk for VTE disease. A number of biological tests (or assays) have been developed for detecting whether an individual is APC-resistant. Generally, these tests assess the anticoagulant response of plasma to the addition of APC.

The original or "classical" APC-resistance assay, known as the aPTT-based test, evaluates the ability of APC to prolong the clotting response of plasma

triggered via the "intrinsic coagulation pathway." The aPTT test has been standardized and is commonly used in clinical laboratories around the world. In the 1990s, Dr. Rosing,[8] developed an APC-resistance assay known as the ETP-based test (often referred colloquially as the Rosing test).[9] The ETP-based test is a measurement of the "extrinsic coagulation pathway" that evaluates the measurement of thrombin generation in plasma triggered with tissue factor (TF) in the presence or absence of added APC.[10]

B. Motion to Exclude Certain Testimony of Dr. David Green

1. Dr. Green's Qualifications

The first part of the Court's analysis of the admissibility of Dr. Green's testimony is to determine his qualifications to address the questions for which the plaintiffs have tendered him as an expert. Dr. Green received an M.D. and Ph.D. in cell biology from New York University. (Green Report, at 2). He is a hematologist with a focus on coagulation disorders.[11] His practice consists of "patients with bleeding and clotting disorders, emphasis on the clotting issues in

[8] Dr. Green refers to the Rosing assay in his report, and Bayer challenges Dr. Green's use of that assay.

[9] The aPTT test and the ETP-based test differ in that the two assays rely on different coagulation triggers and end-points and probe different coagulation pathways.

[10] Initially, the ETP-based test was performed by hand. Since then, the ETP-based test has been revised and is now performed using a measuring apparatus called the thrombinscope. This revised measuring technique is called Calibrated Automated Thrombography (CAT).

[11] Dr. Green did a fellowship in Hematology at Johns Hopkins Hospital from 1993-1994. He did a second fellowship at Memorial Sloan-Kettering Cancer Center in Medical Oncology from 1994-1997. He holds a United States patent on structure-based design and synthesis of FGF (fibroblast growth factor) inhibitors and FGF modulator compounds. He has published extensively on hematology-related issues (see, Curriculum Vitae of Dr. Green)

women in pregnancy and the postpartum period, hormone-related issues with respect to clotting risk." (Green Depo. at 25.) In 1998 he was certified in coagulation for the New York State Department of Health (Green Report, att. 2). He has been the associate director of the special coagulation laboratory of New York University for 15 years. (Green Depo. at 25).

2. Bayer's Challenges To Dr. Green.

Bayer does not challenge Dr. Green's medical qualifications as a hematologist, but does challenge his qualifications to testify on SHBG-related observations, including VTE risks. Bayer argues that Dr. Green is not able to do more than speculate as to the connection between SHBG levels and a VTE risk. In his deposition, Dr. Green stated that he was not an expert on the "underlying scientific basis" for the mechanism that causes SHBG levels to "go up strikingly" in Yasmin-family product users. (Green Depo. at 32.) Green also testified that the rise in SBHG levels was "an important telling observation" which is why it was included in his report. (*Id.* at 33).

It is a requirement of Rule 702 that "the expert explain the 'methodologies and principles' that support his opinion; he cannot simply assert a 'bottom line.'" *Metavante Corp. v. Emigrant Sav. Bank*, 619 F.3d 748, 761 (7th Cir. 2010). Therefore, an expert's opinion is not admissible just on his on say-so, his "ipse dixit." *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). Bayer would have this Court find that Dr. Green's use of clinical data and scientific reports in order to make a connection between SBHG levels and VTE risk is, in fact, ipse

dixit, or just his conclusions. However, the Court is not persuaded that Dr. Green is merely speculating or giving a "bottom line" opinion. Rather, his report and his deposition testimony include observations from the scientific community. Among those on which Dr. Green relied in formulating his report are studies which show that women taking YAZ or Yasmin have higher levels of SHBG. His report provides that SHBG is a "putative marker" for VTE risk. Dr. Green explained, in his deposition, that this means that, "there's solid published data which lead to that conclusion. There are also—there's also literature that speaks to controversy on this point. And so putative, that descriptor is to encompass both sides of the argument, but there's good literature that supports it." (Green Depo. at 43-44). Dr. Green opines that the levels of SHBG "correlate with hormone induced VTE risk." (Relying on the Odlind study -2002).

a. Reliance by Dr. Green on Other Studies

Bayer would have the Court find that because Dr. Green relies on the studies of other scientists and researchers in fields other than hematology to make this conclusion that he has committed improper ipse dixit. However, the Court is not so persuaded. It is reasonable for a hematologist to rely on pharmacologically or epidemologically based studies and reports when opining as to hematological conclusions. Dr. Green's years of medical training and experience qualify him to opine generally the correlations based on his interpretation of pharmacologically and epidemologically based studies and documents. See, e.g. *Doe v. Cutter Biological, Inc.*, 971 F.2d 375, 385 (9th Cir.

1992) ("The fact that the experts were not licensed hematologists does not mean that they were testifying beyond their area of expertise. Ordinarily, courts impose no requirement that an expert be a specialist in a given field, although there may be a requirement that he or she be of a certain profession, such as a doctor."); *Dickenson v. Cardiac & Thoracic Surgery of E. Tenn.*, 388 F.3d 976, 978-79 (6th Cir. 2004); *United States v. Viglia*, 549 F.2d 335, 336 (5th Cir. 1977) (holding that a pediatrician who had degrees in medicine and pharmacology but no experience in treating patients in obesity had sufficient knowledge, training, and education to testify regarding drug's effect on obese persons)).

Dr. Green relied, in part, on studies from related fields which show a correlation between levels of SHBG and VTE risks. Clearly, this correlation would not something that would qualify as "obvious" to a layperson. Dr. Green notes that SHBG is a protein which increases with estrogen exposure in a "dose-dependent" manner. To understand the total estrogenicity of a COC, whatever the generation, the comparative epidemiological studies are relevant. Those studies show increased estrogenicity from second-generation to fourth-generation COCs. (See, Green Report at 5-6). Also relevant to the issue of coagulation is the research which shows that SHBG levels correlate with APC resistance. APC resistance, in turn correlates with increased VTE risk.

Rule 702 states that an expert's testimony must be "based on sufficient facts or data. The Advisory Notes to the 2000 Amendments to Rule 702 make clear that "[t]he term 'data' is intended to encompass the reliable opinions of other

experts." Relying on the published works of other professionals is permissible in medicine, as it is in other fields. 33A Fed. Proc., L.Ed. § 80:251 (2008). The Supreme Court noted that "a judge assessing a proffer of expert scientific testimony under Rule 702 should also be mindful of other applicable rules." *Daubert,* 509 U.S. at 595. The Court explicitly suggested that lower courts consider Federal Rule of Evidence 703, which permits experts to use facts or data "of a type reasonably relied upon by experts in the particular field."

While the objections raised by Bayer identify potential weaknesses in Dr. Green's conclusions, they do not demonstrate that Dr. Green's correlation determinations are unsound. Accordingly, these objections do not warrant exclusion. Bayer may vigorously attack any relevant aspect of Dr. Green's conclusions or the basis of his opinions on cross-examination, as well as question him on any evidence that contradicts his opinions. Bayer's competing experts may also address any of the objections discussed above. Therefore, the Court **FINDS** that Dr. Green's testimony may include references to epidemiologic studies; that he may, from his review of research and scientific studies, make the correlation between SHBG and VTE . Accordingly, the Court **DENIES** Bayer's motion to exclude the testimony of Dr. Green on the SHBG and VTE correlation.

b. Dr. Green's Reliance on the Rosing Assay.

The Court has previously found that Plaintiffs may use the testimony of Dr. Rosing, and his study, commonly referred to as the "Rosing assay." See CMO 49. Bayer asserts that Dr. Green should not be allowed to testify as to APC resistance

and use of YAZ and Yasmin. In light of the previous discussion and the admission of the testimony of Dr. Rosing, the Court **DENIES** Bayer's motion to exclude the testimony of Dr. Green on the use of YAZ and Yasmin and APC resistance.

c. Dr. Green's Use of Foreign Regulatory of DRSP-containing COCs

Bayer asserts that Dr. Green should not be permitted to opine on any significance of regulation in Europe and the United States on YAZ and Yasmin. In his report, Dr. Green provides that the European Active Surveillance study and a case-controlled study using US data and UK data on VTE risks associated a higher risk with third-generation COCs. Dr. Green notes, in his report, that "the significance of the findings has been recognized by regulatory authorities both in the United States and in Europe," that a labeling change was recommended, and that the FDA noted that the European label was updated and that the FDA is reviewing the labeling issue (Green Report at 4-5).

In this instance, Dr. Green's report opinions are not *based* on the regulatory outcome of the other countries but, rather, are based on the scientific opinions expressed by experts in the foreign regulatory agencies, and the actions taken by those agencies in response. *See Daubert*, 509 U.S. at 592 ("[A]n expert is permitted wide latitude to offer opinions, including those that are not based on first[-]hand knowledge or observation."). His report includes a summary of the current status of those regulatory actions which are appropriate summaries of the underlying documents that he reviewed. *See* Fed. R. Evid. 1006 (permitting

summary evidence); *United States v. Pree*, 408 F.3d 855, 869-70 (7th Cir. 2005)(approving use of an "expert summary witness" who is permitted both to summarize evidence for the jury and to offer an expert analysis of the facts). Green may testify about these matters. "[A]ny questions or problems concerning the expert's testimony may be thoroughly explored during cross-examination of the witness." *United States v Gonzalez*, 933 F.2d 417, 429 (7th Cir. 1991). Consistent with his report and his expertise, the Court will permit Dr. Green to testify of the regulatory status, based on his review of those foreign studies.

V. CONCLUSION

Accordingly, the Court **DENIES** Bayer's motion to exclude the testimony of Plaintiffs' expert, Dr. David Green, M.D., Ph.D. as set forth above.

IT IS SO ORDERED.

David R. Herndon
2011.12.16
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CHIEF JUDGE
UNITED STATES DISTRICT COURT **December 16, 2011**